UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GARY C. STARLING and JOSHUA N. FINGER

Appeal No. 2005-2121
Application No. 09/745,605

ON BRIEF

Before SCHEINER, ADAMS and MILLS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves an isolated nucleic acid molecule encoding a protein designated APEX-1,[1] said to be a member of the CD2 subgroup of the immunoglobulin superfamily. The examiner has rejected claims 1-5 and 53-65, all of the claims subject to appeal,[2] as lacking patentable utility and enablement. In addition, the examiner has rejected certain claims as indefinite, as anticipated, and as lacking adequate written descriptive support. We have jurisdiction under 35 U.S.C. § 134. We affirm the rejections for lack of utility and enablement, and do not reach the remaining rejections.

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[1] "The acronym 'APEX' or '*apex*' stands for Antigen Presenting cell EXpression, although the transcript expression pattern of the *apex* genes is not restricted to [antigen presenting cells]' (Specification, page 3).

[2] Claims 6-14, 27-41 and 43-52 are also pending, but have been withdrawn from consideration.

BACKGROUND

The present invention is directed to *apex-1*, a nucleotide sequence "predicted to encode [APEX-1, a] new member[ ] of the immunoglobulin superfamily" "which possess[es] structural features shared with the CD2 subgroup [of the Ig superfamily,]" including "[an] N-terminal signal peptide, an extracellular domain or region having Ig-like features, a hydrophobic transmembrane domain, and a C-terminal intracellular or cytoplasmic domain" (id., page 7).

The specification does not disclose any specific activity or function associated with APEX-1, but teaches that members of the immunoglobulin superfamily generally "mediate diverse biological events including leukocyte proliferation, differentiation, migration, and activation" (id., page 1), and that the CD2 subgroup of the Ig superfamily "consists primarily of cell-surface receptors that regulate adhesion among different leukocytes and generate co-stimulatory signals" (id.). Based on the asserted structural similarity to members of the CD2 subgroup, appellants suggest that "APEX proteins may play a role as cell-surface receptors that regulate adhesion among different leukocytes and generate co-stimulatory signals" (id., page 7).

The specification discloses that APEX-1 "can be used to map the location of [its] corresponding gene[ ] and other related naturally occurring genomic sequences" (id., page 46), and can also "be used to access and elaborate functions of APEX proteins" (id.).

In addition, the specification discloses that "[s]tructural similarity in the context of sequences and motifs between APEX and proteins defined by CD antigens suggests that APEX proteins may be a potential target for diseases such as inflammation, cancer

and immune disorders" (id., page 54). Thus, according to appellants, detection of APEX-1 or its RNA transcripts in abnormal amounts can be used to diagnose or monitor the course of "a disease associated with the presence or absence of the [APEX-1] protein" (id., pages 47 and 48). Similarly, the specification discloses that the present invention can be used to treat disorders associated with abnormally decreased or increased APEX-1 activity or expression (id., pages 54 and 55).

DISCUSSION

Utility

The examiner rejected claims 1-5 and 53-65 under 35 U.S.C. § "because the claimed invention is not supported by either a specific and/or substantial utility or a well established utility." Answer, page 3. The claims stand or fall together. Appeal Brief, page 4. We will focus on claim 1, which reads as follows:

1. An isolated nucleic acid molecule encoding APEX-1.

The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility.").

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to an expressed sequence tag – a short nucleotide sequence encoding a fragment of a protein expressed in a particular tissue, at a particular point in time. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir.

2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The court held that disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that the claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373, 76 USPQ2d at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of

the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

The examiner notes that "the specification fails to disclose any particular function or biological significance" for APEX-1. Answer, page 4. Appellants argue that APEX-1 "is homologous to the CD2 subfamily, which is well-characterized as having utility with respect to leukocyte proliferation, differentiation, migration and activation, and diseases associated therewith" (Brief, pages 7-8), and "homology to a molecule with known utility is acceptable for establishing Section 101 utility" (id., page 8). Nevertheless, the examiner argues that the specification does not disclose the degree of homology between APEX-1 and any particular member of the CD2 subfamily, and in any case, "[a]ssignment to this family does not support an inference of utility because the members are not known to share a common utility" (Answer, page 16). That is, "no activit[ies] [are] known to be common to all members of the CD2 subfamily[,]" and "there is no evidence that the . . . APEX-1 polypeptide would share any one of those different activities" (id., page 15). The examiner concludes that "[t]he instant claims are drawn to a nucleic acid encoding a polypeptide of as yet undetermined function or biological significance" (id., page 5), without an "immediately apparent or 'real world' utility as of the filing date" (id.).

With respect to appellants' assertion that APEX-1 is useful "for diagnosing . . . a disease associated with the presence or absence of the APEX protein" (Specification, page 47), the examiner notes that "the specification does not disclose a nexus between any specific disease states and a change in the amount or form of APEX genes" (Answer,

page 14). The examiner concludes that "[s]ignificant further research would have to be conducted to identify such a nexus" (id.). In other words, the examiner finds that the claimed invention does not provide a well-defined, particular benefit to the public.

A substantial utility is one that makes the invention useful to the public in its current form, not potentially useful in the future after further research. See Fisher, 421 F.3d at 1371, 76 USPQ2d at 1230. As the examiner has pointed out, the specification provides no guidance on the meaning of an increase or decrease in APEX-1 expression or activity, other than a hypothetical association with inflammation, cancer and/or immune disorders. Thus, we agree with the examiner that the specification fails to disclose a substantial utility that satisfies the requirements of 35 U.S.C. § 101.

To the extent appellants argue that "credible utility is established at the very least by the use of the claimed compounds as molecular weight markers," (Brief, page 8) we disagree. A utility that could be asserted for any expressed human gene is not a "specific" utility that will satisfy § 101. See Fisher, 421 F.3d at 1370, 76 USPQ2d at 1230 (a specific utility requires "that [the] claimed invention can be used to provide a well-defined and particular benefit to the public") and id. at 1374, 76 USPQ2d at 1232 ("Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101").

Any expressed human gene could be used as a molecular weight marker – just as any expressed gene "can be used to map the location of [its] corresponding gene[ ]

and other related naturally occurring genomic sequences" (Specification, page 46), as well as "to access and elaborate [its own] functions" (id.). Therefore, those potential uses are not specific to the claimed polynucleotides and do not satisfy the requirements of § 101.

We conclude that the specification does not does not disclose a specific and/or substantial utility for the claimed polynucleotides. Accordingly, we affirm the rejection of claims 1-5 and 53-65 under 35 U.S.C. §101.

Enablement

Claims 1-5 and 53-65 also stand rejected under 35 U.S.C. §112, first paragraph, as "the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility . . . [and therefore], one skilled in the art would not know how to use the claimed invention" (Answer, page 6). To the extent that this enablement rejection is a corollary of the examiner's finding of lack of utility, we agree.

Accordingly, the rejection of claims 1-5 and 53-65 as lacking enablement under the first paragraph of 35 U.S.C. §112 is affirmed.

SUMMARY

The specification does not disclose a specific and substantial utility for the claimed polynucleotides. We therefore affirm the rejections of claims 1-5 and 53-65 under 35 U.S.C. §§ 101 and 112, first paragraph. Our affirmance of these rejections constitutes a disposition of all the claims on appeal. Accordingly, we do not reach the remaining rejections for indefiniteness, anticipation and lack of written descriptive support.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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